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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/037,657	03/10/1998	TRACY WILLSON	10857Z	7400

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Office Action Summary	Application No.	Applicant(s)	
	09/037,657	WILLSON ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40,42-47,57 and 58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40,42-47,57 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1a. Receipt of Applicants' arguments and amendments filed on 06 December 2004, is acknowledged. Claims 42 and 57 have been amended and new claim 58 has been added. Claims 40, 42-47 and 57-58 are pending and under consideration.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed in Paper No: 29, filed on 12/06/04:

(I) The rejection of claims 42 and 57made under 35 U.S.C § 112, second paragraph, for not reciting "complement", is withdrawn, because applicants amended the claims to recite "complement".

Response to Applicants' arguments:

3. Claim Rejections - 35 U.S.C. §101/112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3a. The rejection of claims 40, 42-47, 57 made under 35 U.S.C. 101 is maintained and new claim 57 and new claim 58 is also rejected under the same statute, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The instant claims are directed to an isolated hemopoietin receptor comprising the amino acid sequence set forth in SEQ NO:13, 15, 1 7, 1 9 or 25 and nucleic acid encoding said receptor. The specification describes the polypeptides of the instant invention as being a novel haemopoietin receptor, (page 3, lines 10-14).

Applicants argue that the claimed receptor "NR6", is explicitly characterized in the specification as a member of the haemopoietin receptor family. Applicants also argue that Dr. Hilton's Declaration previously submitted discloses that NR6 results in reduced blood cell production and that NR6 is lethal during embryonic development or immediately after birth enables the detection of potential birth defects or potential dysfunction to haemopoiesis.

It is found persuasive that the NR6 used to establish the knockout mice would have a "real world" utility for diagnostic purposes, because it can be used in predicting birth defects. It is also found persuasive that the NR6 receptor which results in reduced blood cell production, would also be found useful therapeutically, in the regulation of haemopoieses. However, the instant specification does not disclose which polypeptide was used to carry out the knockout mice experiments or was shown to reduce blood cell production. The instant claims are drawn to polypeptide of SEQ ID NO: 13, 15, 17, 19, 25 or 44. It appears that these are disparate sequences, for example SEQ ID NO:13 comprises 413 amino acid residues and is designated as murine NR6.1, SEQ ID NO:17 is designated as murine NR6.3 and comprises a 155 amino acid residues, while SEQ ID NO:19 comprises 278 residues and is artificial sequence and SEQ ID NO:25 comprises 350 amino acid resides and is designated as human NR6, (see table 3 on page 29). Thus, Example 15 on page 56 of the instant specification discloses the generation of knockout mice lacking NR6 receptor, however, there is no disclosure of which polypeptide sequence was used to generate said knockout mice. The instant specification does not clearly indicate whether each of SEQ ID NO:13, 17, 15, 25 or 44

was deleted to generate a knockout mice lacking that specific sequence. Neither do the Applicants disclose that all of these sequences resulted in reduced blood cell production.

Accordingly, claims 40,42-47, 57 and 58 not are not supported by either a specific and substantial asserted utility or a well established utility, unless Applicant discloses which one of the polypeptides of SEQ ID NO:13, 17, 15, 25 or 44 was found to result in reduced blood cell production and was found lethal during embryonic development or immediately after birth. Once Applicant discloses said polypeptide, this rejection will be withdrawn for said receptor polypeptide.

4b. Claims 40, 42-47, 57 and 58 are also rejected under 35 U.S.C. 1 12, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Although Applicant's argument that NR6 results in reduced blood cell production and was found lethal during embryonic development or immediately after birth, is found persuasive, one of ordinary skill in the art would not know which one of the polypeptides of SEQ ID NO:13, 17, 15, 25 or 44 is NR6, and therefore, would not know how to use the polypeptide of SEQ No: 13, 15, I 7, 19, 25 or 44. The disclosure of which polypeptide was shown to result in reduced blood and was found lethal during embryonic development or immediately after birth would obviate this rejection.

Conclusion:

4. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
03 March 2005

JANET ANDRES
PRIMARY EXAMINER